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ASPECTS OF TREATMENT*

How should the common bile duct be explored?

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Summary

An attempt has been made to find which of 3 operations currently in use for exploring the bile ducts gave the best clinical results. For this purpose 3 series of consecutive patients treated at The London Hospital over a 12-year period have been studied retrospectively. The operations used were as follows: (1) conventional supraduodenal choledochotomy; (2) transduodenal biliary sphincterotomy; and (3) a combined approach.

The mortality in the supraduodenal series was 4 (4%) of 101 patients and in the transduodenal series 2 (2.4%) of 82 patients. Both routes were used in 26 patients, of whom 2 (7.7%) died. Early complications were commoner after choledochotomy than after biliary sphincterotomy, but when both procedures were combined the incidence was higher still. Late complications were also more frequent after both the supraduodenal and the combined approach, residual or recurrent stones and cholangitis being 6 times more common than after sphincterotomy alone. Postexploratory cholangiography, however, was not used routinely in the supraduodenal series and might conceivably have reduced this factor further, but not below 3. Stenosis occurred in one patient after choledochotomy and in one patient after the combined operation but not after sphincterotomy alone.

In this study, therefore, transduodenal biliary sphincterotomy gave the lowest mortality and morbidity. With the combined procedure, however, the mortality and morbidity were much higher than after either method alone.

Introduction

In current surgical practice there are 3 main methods for exploring the common bile duct.

*Fellows interested in submitting papers for consideration with a view to publication in this series should first write to the Editor.

Access to the duct may be gained by opening it as it lies in the free border of the lesser omentum or, after opening the duodenum, by incising the biliary sphincter at its outlet. Less frequently both approaches are used at the same operation.

In Britain the supraduodenal approach with subsequent T-tube drainage is the conventional operation, and many surgeons regard this as the method of choice. It is, however, by no means trouble-free, and attention has from time to time been drawn to some of its disadvantages. Assessment of the sphincteric region at operation is difficult[1] and blind dilatation may lead to the creation of a false passage[2] or the subsequent development of a stricture[3]. Stones may be overlooked and numerous authors quote the incidence as ranging from 4.7 to 12.1%[4-6].

The transduodenal approach to the common bile duct was first described by Kocher in Vienna in 1895[7]; 3 years later McBurney[8] in New York recommended its use for the removal of the stone impacted at the lower end of the common bile duct. Subsequent interest remained sporadic until the last decade. It is apparent from a study of the literature that surgeons in Belgium, Argentina, France, Czechoslovakia, Italy, and Austria favour this approach. Although in Britain the use of this route was recommended some 15 years ago[9,10], it has only recently attracted much attention[11-13].

A search of the literature has revealed only 2 contributions in which the long-term results of these 2 approaches to the bile duct have been compared[14,15]. In both cases conclusions were drawn in favour of the transduodenal approach, but apart from a classification of results as excellent, moderate, or poor few details were given. The outcome of exploring the biliary tree by both routes simultaneously does not seem to have been compared with that following exploration by either route alone.

It seemed appropriate, therefore, to attempt a more detailed comparison of these operations. Accordingly a consecutive series of patients whose biliary tree was explored in the conventional way only (supraduodenal series) has been studied. The findings were compared with those obtained from a similar series of patients whose bile ducts were explored by the transduodenal route only (transduodenal series) and a third series in which both procedures were used at the same operation ('combined' series).

In lectures delivered to the Académie de Chirurgie in Paris in 1959 Champeau[16] and Longuet[17] stated that the long-term effects of biliary sphincterotomy were unknown and certain questions should be asked. Does stenosis develop at the site of operation? How often is the sphincter rendered incompetent? Does biliary reflux occur and does it cause cholangitis? Does the presence of duodenal contents in the bile ducts lead to impaired liver function? To these we may add two further questions. What is the incidence of recurrent stone? Does postoperative pancreatitis occur? Satisfactory answers to the above questions are still lacking. In this paper, therefore, we also present some special studies which were made on both the transduodenal series and the series treated by the combined routes in an attempt to answer these questions.

Case material and methods

Our concept of the anatomy and operative technique for transduodenal biliary sphincterotomy has been described elsewhere[18]. By biliary sphincterotomy we mean division of the common sphincter (sphincter papillae) and the distal part of the biliary sphincter (sphincter choledochus). The extent of the incision is such as to allow the bile ducts to be explored with Desjardin forceps and the removal of stones. The incision does not extend proximally beyond the duodenal wall and

does not, therefore, divide all of the fibres of the sphincter choledochus. The cut mucosal edges are not sutured.

There were 101 patients in the supraduodenal series, 82 patients who underwent biliary sphincterotomy alone, and 26 patients who had the combined procedure during the 12-year period 1959–71 inclusive.

In respect of age and sex distribution the series were similar. In the supraduodenal series there were 69 women and 32 men aged 22–79 (mean 55.8) years; in the transduodenal series there were 48 women and 34 men aged 27–81 (mean 56.0) years; in the third series (combined procedure) there were 17 women and 9 men aged 45–81 (mean 59.2) years. The operative findings, summarized in Table I, were also similar. At the time of operation 51 of the supraduodenal series, 42 of the transduodenal series, and 14 of the 'combined' series were jaundiced. Gallbladder stones were found in all patients who had not previously had the organ removed, and most had stones in the bile ducts as well. The remaining patients had some degree of hold-up at the outlet.

A comparison of the results of these 3 procedures was made in terms of mortality, length of stay in hospital, and incidence of early and late postoperative complications.

Additional studies were carried out on the transduodenal and the 'combined' series. These patients were asked to complete a questionnaire similar to that devised by Visick[19], liver function tests were done, and on 51 patients hypotonic duodenography was carried out in an attempt to detect reflux into the biliary tree. For this the method described by Liotta *et al.*[20] was modified by omitting the intraduodenal instillation of a local anaesthetic and by using the anticholinergic drug oxyphenonium (4 mg). Twenty patients with an intact sphincter acted as controls. In 5 patients (Cases 1–5, Table V) the arrival time for bromsulphalein (BSP) in duodenal aspirate was determined by the method of Caroli and Tanasoglu[21]. The plasma amylase level was estimated by Harrison's method[22] in 14 consecutive patients before and at intervals of 24 and 48 h after biliary sphincterotomy.

Results

Mortality After the supraduodenal operation alone 4 patients died, one from biliary peritonitis, one as a result of myocardial infarction, one from haemorrhage from a gastric ulcer and renal failure, and one from septicaemia, cholangitis, and a subphrenic abscess. Three were over the age of 65 years and 3 were jaundiced at the time of operation. After the transduodenal operation alone 2 patients died, one from subphrenic abscess and one from pulmonary embolism. Where both routes had been employed 2 patients died, one from acute pancreatitis and the other from bronchopneumonia. All of the patients dying after biliary sphincterotomy or the combined operation were over 65 years of age and 2 were jaundiced.

Length of stay in hospital There was no statistically significant difference in the length of stay in hospital between the two

TABLE I *Comparison of operative findings*

	Supraduodenal series	*Transduodenal series*	*'Combined' series*
	(101 patients)	*(82 patients)*	*(26 patients)*
Common bile duct stones	67	55	17
Sphincter stenosis	34	27	9

main series, the mean for the supraduodenal series being 1.5 days longer than for the transduodenal series. The mean length of stay for the 26 patients undergoing the combined procedure (4.5 days) was significantly longer ($P < 0.05$) than that for the supraduodenal series.

Early postoperative complications These are summarized in Table II. The incidence of acute pancreatitis, biliary peritonitis, biliary fistula, and cholangitis was limited to cases in the supraduodenal and 'combined' series where a T tube had been inserted. These were not seen in the transduodenal series, but one patient developed a duodenal fistula which closed spontaneously and another required reoperation for duodenal obstruction.

Late complications These are summarized in Table III and are discussed in more detail below. Those not directly related to the type of approach to the bile duct—for example, incisional herniae—have been excluded.

Residual or recurrent stone; cholangitis

Supraduodenal series Nine patients are known to have had and 3 are suspected of having residual or recurrent stones. All were found to have stones in their bile ducts at the original operation, although satisfactory pre- or peroperative cholangiograms had been obtained in only 6 of these.

Postexploratory peroperative cholangiography had not been used routinely in this series but all 12 of the above patients had had postoperative T-tube cholangiograms with the following results. Stones were shown to have been left behind in 4 patients. In 2 the ducts were re-explored and the stones removed. In the remaining 2 the surgeon ad-

TABLE II *Early postoperative complications*

	Supraduodenal series (101 patients)	*Transduodenal series (82 patients)*	*'Combined' series (26 patients)*
Acute pancreatitis	1	0	1
Biliary peritonitis	1	0	2
Biliary fistula	1	0	1
Duodenal fistula	0	1	0
Duodenal obstruction	0	1	0
Subphrenic abscess	3	5	3
Cholangitis	5	0	3
Wound infection	17	10	10
Pulmonary embolism	4	3	1
Mortality	4 (4%)	2 (2.4%)	2 (7.7%)

TABLE III *Late complications*

	Supraduodenal series (97 patients)	*Transduodenal series (80 patients)*	*'Combined' series (24 patients)*
Cholangitis	10	1	2
Common bile duct stones			
Necessitating reoperation	9 (9.3%)	1 (1.3%)	2 (8.3%)
Suspected clinically	3	0	0
Stenosis/stricture	1	0	1
Pancreatitis	0	0	0

judged that they might pass spontaneously. Both, however, subsequently developed cholangitis and underwent re-exploration with removal of stones. T-tube cholangiography was inconclusive in 4 patients, but re-exploration was not considered justified. Since then one has developed cholangitis and was found at reoperation to have stones. The other 3 are believed on clinical grounds to have had cholangitis, but intravenous cholangiography has not yet revealed a stone. In the remaining 4 patients T-tube cholangiography revealed no abnormality. All 4 have since developed recurrent cholangitis, with stone formation confirmed at reoperation.

From the above it can be seen that 10 of these 12 patients developed cholangitis, of whom 7 are known to have had stones and in 3 the presence of stones is suspected.

Transduodenal series Cholangitis and stones recurred in one patient in this series. She was referred to us with jaundice some years after biliary surgery elsewhere. A sphincterotomy was carried out with removal of stones from the bile ducts. Three years later re-exploration was undertaken for repeated attacks of cholangitis. In addition to stones in the bile duct an intrahepatic gallbladder, its duct blocked by a stone, was found and removed. The sphincterotomy stoma was 9 mm in diameter, but the stones were too large to pass spontaneously.

'Combined' series Two patients presented 6 and 9 years respectively after operation with cholangitis and were subsequently found to have large common duct stones. In the first patient preoperative intravenous cholangiography had revealed multiple stones. There was a suspicion of a filling defect at the lower end of the common bile duct on the T-tube cholangiograms, but clamping and extraction of the T tube had been uncomplicated. In the second patient operative cholangiography had revealed a solitary stone, which was removed, and the subsequent T-tube cholangiograms had shown no filling defects, with free flow of contrast medium into the duodenum.

Stenosis

This occurred in one patient 4 years after choledochotomy with the passage of Blake's dilators and also in an elderly woman 3 years after combined supra- and transduodenal exploration of her bile duct. At reoperation the first patient had recurrent stones and a fibrous stricture at the lower end of the common bile duct above the papilla. In the second patient the sphincter choledochus was found to be intact but the papillary orifice had stenosed. There were no recurrent stones. A sphincterotomy was carried out which relieved some of her symptoms and caused the plasma alkaline phosphatase level to fall from 39 to 16 King–Armstrong units.

Pancreatitis

There was no evidence that acute or chronic pancreatitis was a late complication after any

TABLE IV *Analysis of answers to questionnaire*

Visick grade		*Transduodenal series (71 patients)*	*'Combined' series (24 patients)*
1	Asymptomatic	52	19
2	Mild symptoms not requiring treatment	14	3
3	Mild symptoms interfering with quality of life and requiring treatment	5	2
4	Made worse: severe symptoms incapacitating patient	0	0

of the procedures. In one man known to have had common bile duct stones and chronic pancreatitis preoperatively sphincterotomy has not alleviated his symptoms.

Special studies in transduodenal and combined series

Questionnaire and liver function tests

The results of the questionnaire, representing the patient's subjective assessment of his own state of health, are summarized in Table IV. Of the 104 patients surviving biliary sphincterotomy alone or the combined procedure, 4 were not traced and a further 5 had died from intercurrent disease (ischaemic heart disease in 3, carcinoma of the bronchus in another, and carcinoma of the breast in a fifth). Autopsy showed no evidence of hepatobiliary or pancreatic disease in the 2 patients dying of malignant disease but was not performed on the other 3 patients. Of the remaining 95 patients, 88 (92.6%) claimed that the results of surgery were excellent or that they had been improved by it (Visick Grades 1 and 2), results which were supported by the findings on physical examination.

Details of the 7 patients who expressed dissatisfaction with their clinical condition are given in Table V. Pain was the predominant symptom in all of these. In 3 (Cases 1, 2, and 3) it may be explained by other pathology, since intravenous cholangiography revealed no evidence of stone or stenosis. In Case 7 the cholangiogram also showed a patent biliary tract. In Cases 1–5 hypotonic duodenography failed to demonstrate reflux (vide infra), but the duodenal arrival time of injected BSP was within normal limits. One patient (Case 6) refused all further investigations.

Routine liver function tests were carried out on 85 patients when the questionnaire had been completed. Plasma bilirubin levels were below 17 μmol/l (1 mg/100 ml) in

TABLE V *Analysis of unsatisfactory results (Visick Grade 3) after sphincterotomy*

Patient and Sex	*Age*	*Operation*	*Pathology*	*Associated pathology*	*Symptoms*	*Liver function tests*	*Intravenous cholangiogram*	*Reflux on hypotonic duodenography*	*BSP arrival time*
1 M	46	SDC and TDS	Stones	Chronic pancreatitis	Pain, weight loss	Normal	NAD	Absent	Normal
2 M	61	TDS	Stones	Hiatus hernia	Pain, acid reflux	Normal	NAD	Absent	Normal
3 F	55	TDS	Stenosis	Hiatus hernia	Pain, vomiting	Normal	NAD	Absent	Normal
4 F	72	TDS	Stenosis	—	Pain, diarrhoea	Normal	R	Absent	Normal
5 F	48	TDS	Stenosis	—	Pain	Normal	S	Absent	Normal
6 F	55	TDS	Stenosis	—	Pain, flatulence	Normal	R	R	R
7 F	74	SDC and TDS	Stenosis	Osteoporosis, vertebral collapse	Pain, weight loss	AP = 16 KAU	NAD	R (Air in biliary tree on plain X-ray)	R

SPC = supraduodenal choledochotomy; TDS = transduodenal biliary sphincterotomy; R = test refused; NAD = no evidence of stone or stenosis; S = hypersensitivity to iodine; AP = alkaline phosphatase; KAU = King-Armstong units.

all of these. The plasma alkaline phosphatase level was raised in 4 patients, including the elderly woman with stenosis of the papillary orifice following the combined procedure. The remaining 3 were asymptomatic. All had undergone biliary sphincterotomy alone. Reflux during hypotonic duodenography occurred in one of these. Flocculation tests were abnormal in one patient who suffers from chronic alcoholism.

Hypotonic duodenography In a control series of 20 patients with an intact biliary sphincter hypotonic duodenography failed to demonstrate reflux. The findings in 51 patients after sphincterotomy are shown in Table VI. In 10 patients (20%) gas was observed in the bile ducts on plain X-ray. During hypotonic duodenography, however, reflux occurred in these and in 10 further patients (40%). Both biliary and pancreatic duct systems were outlined by barium in 6 of these patients. The choledochoduodenal junction was situated in an abnormal site in 3.

Nineteen of the 20 patients with reflux demonstrated during hypotonic duodenography had no clinical evidence of cholangitis or pancreatitis. The remaining patient had residual stones, but although reflux persisted after their removal, cholangitis has not recurred. The presence of reflux was not associated with a poor symptomatic result as judged by the answers to the questionnaire. Comparison of patients with and without reflux showed that there was no significant difference in the mean age or the length of follow-up.

TABLE VI *Results of hypotonic duodenography in 51 sphincterotomized patients (1–12-year follow-up)*

Preliminary abdominal radiograph	
Bile ducts outlined with air	10
Duodenography	
Bile duct	
No reflux	31
Reflux	20
Pancreatic duct	
No reflux	45
Reflux	6

Plasma amylase levels The preoperative value was within the normal range (4–32 Wohlgemuth units) in 13 of the 14 patients in whom it was determined. Abnormal values, from 64 to 256 Wohlgemuth units, were obtained during the first 24 h after sphincterotomy in 5 patients but had returned to normal within 48 h. None of the 14 patients had any clinical evidence of acute pancreatitis.

Discussion

The mortality of 4% following supraduodenal choledochotomy is in accord with other series. Glenn and Beil[23] reported a mortality of 5.6%. Colcock and Perey[24] achieved a mortality of 1.8% in 503 patients, although stones were found in only 139 of their cases. Our mortality of 2.4% in the transduodenal series may be compared with that of 5% among 6,291 cases collected from the literature[25], although lower figures have been reported. In a study comparing choledochotomy and biliary sphincterotomy Lauras *et al.*[14] found the mortality to be equally high (8%) in both. Niederle [15], however, in Czechoslovakia reported a higher mortality after biliary sphincterotomy (2.9%) than after choledochotomy (1.8%). He gave no further details. Where the two approaches were combined 2 patients (7.7%) died. Although the series was small, consisting of only 26 patients, this last procedure would appear to be the most hazardous of the 3 studied.

Acute pancreatitis is a well-recognized postoperative hazard of biliary surgery and certain authors have indicated that it may be particularly frequent after the trans-

duodenal approach[26]. In our study this complication occurred in one patient in the supraduodenal series and one in the 'combined' series but not after transduodenal sphincterotomy alone. It is a serious complication associated with a mortality of 85% according to Hepp and Bismuth[27]. Suggested aetiological factors include the use of a transpapillary drain, forceful use of sounds, obstruction of the pancreatic duct orifice by oedema from a long traumatic operation or by a suture, and reflux of infected duodenal contents[27]. Previous pancreatitis may be an important factor[28] and may in part explain the low incidence in our study when compared with others from Europe, where all forms of pancreatitis seem to occur more frequently[29]. A transient rise in plasma amylase level occurred in approximately one-third of our patients after biliary sphincterotomy. A similar figure has been reported after supraduodenal choledochotomy by Keighley and Graham[30].

Cholangitis in the early postoperative period occurred only in patients in whom the biliary tree had been drained externally after either the supraduodenal or combined approach. It is a well-recognized complication of the use of T tubes[6] and is not necessarily related to the presence of stones in the bile duct at operation[31].

With regard to the late complications of biliary sphincterotomy Roux *et* al.[32] and Moreaux and Teixeira[33] have suggested that cholangitis is caused by reflux. In all three series in the present study, however, its occurrence strongly suggested the presence of stone. In the transduodenal and 'combined' series cholangitis occurred in 3 patients and stones were found in each. In 2 of these patients after removal of the stones and in 18 others who were examined reflux was demonstrated on hypotonic duodenography, but none is known to have cholangitis. There was therefore no evidence from this study that reflux is a cause of clinically recognizable cholangitis.

There was no clear evidence on clinical grounds or from liver function tests that hepatic function was impaired after biliary sphincterotomy, nor has this been a sequel to choledochoduodenostomy[34,35]. Reflux of duodenal contents has been reported by Capper[34] and by Johnson and Stevens[36] to occur in the majority of patients after biliointestinal anastomosis, but these authors did not report that it was associated with liver damage. We present evidence elsewhere[37] that abnormal degrees of BSP retention in plasma may occur in 30% of patients after sphincterotomy. This, however, is no greater than has been reported after choledochotomy[38,39].

The importance of adequate stoma size in the prevention of stenosis with subsequent cholangitis has been stressed by several different authors[34-36]. Niederle[15] reported that stenosis occurred in less than 2% of 345 patients after sphincterotomy, which agrees with our findings, stenosis occurring in one patient after the combined procedure.

It must be recognized that the methods we have used for detecting stenosis are relatively crude, being confined to clinical assessment and serial liver function testing. It could be argued that where reflux was not seen during hypotonic duodenography (60%) this might be due to stenosis. We have, however, carried out a more complex study designed to demonstrate subclinical degrees of stenosis after sphincterotomy which is described elsewhere[37]. This suggested that stenosis may in time develop in up to 4% of these patients, although it has not yet done so. Some consider that mucosa-to-mucosa suture is advisable to insure against the development of stenosis[40]. Our findings suggest that it is unnecessary and we have endoscopic confirmation of this[18].

The known incidence of overlooked or recurrent stone in the supraduodenal series was 9.3% (9 cases, Table III) and stones are suspected to be present in a further 3 cases. Could this incidence have been lowered by more extensive use of radiology? Intravenous and pre-exploratory peroperative cholangiography are of value in demonstrating the presence of stones in the bile ducts but can be misleading when estimating the number present[5]. Bile duct stones were in fact found at the first operation in all 12 patients. The importance of the postexploratory intraoperative T-tube cholangiogram in the detection of residual stones has been stressed by several authors[5,41,42]. It would be reasonable to suppose that the 4 patients found to have residual stones on postoperative T-tube cholangiography would have had these detected by such studies and dealt with at the time. It is well recognized, however, that spasm of the lower end of the common bile duct or air bubbles may give rise to difficulty in interpretation of the postexploratory radiographs in one-third of cases[41]. In the present study a similar proportion of postoperative T-tube cholangiograms were inconclusive and if these results had been obtained at the time of operation the question as to whether reopening the duct would have been justifiable arises. Recurrent bile duct stones were, however, subsequently removed from 4 patients who had had normal postoperative T-tube cholangiograms and it would seem unlikely that postexploratory cholangiography would have altered this. Thus of the 12 patients with known or suspected residual or recurrent stones the addition of postexploratory cholangiography might at best be expected to have detected them in 8. This still leaves a minimum incidence for recurrent stone of 4% in the supraduodenal series. Nonetheless, these data would suggest that routine postexploratory cholangiography may be worth while if supraduodenal choledochotomy is to be used.

After sphincterotomy interpretation of the postexploratory cholangiogram can be difficult since the dye tends to run out into the duodenum. This may be counteracted by tilting the table to the head-down position and inserting a small Foley catheter through the divided sphincter. Its omission, however, in most cases in our transduodenal series would appear to be justified by the low recurrence rate for stone (1.3%).

The incidence of residual or recurrent stone after choledochotomy was several times higher than after biliary sphincterotomy. It is difficult to be certain of the explanation for this. In our view 2 factors are involved: sphincterotomy achieves a more complete clearance of debris and small stones from the lower end of the common bile duct and the resulting patent stoma may permit those that are left behind to pass spontaneously.

Within the limits of this study, therefore, the answers to the questions posed by Champeau and Longuet in 1959[16,17] and by ourselves might be summarized as follows:

1) Stenosis does not occur after biliary sphincterotomy of the type used in this series. If however, only a limited papillotomy is made and the distal fibres of the sphincter choledochus are not divided, then it may do so.

2) Hypotonic duodenography has shown that in 40% of cases the sphincter can be rendered incompetent after sphincterotomy.

3) It follows that reflux may occur in up to 40% of cases, although there was evidence of gas in the biliary tree in only 20%. It was not associated with clinical evidence of cholangitis unless a stone was present.

4) There is no evidence clinically or from routine liver function tests that hepatic function deteriorates after biliary sphincterotomy.

5) After cholecystectomy and biliary sphincterotomy alone the known incidence of recurrent or residual stone in this series is nil.

6) Acute pancreatitis does not seem to occur after biliary sphincterotomy alone in our area. It was, however, seen in one case after the combined approach when a T tube had been inserted.

From this it will be seen that transduodenal biliary sphincterotomy gave better results than either supraduodenal choledochotomy or when both operations were combined into one procedure. It would appear, however, from the higher mortality and frequency of serious complications that the combined procedure has less to justify it than the use of either procedure alone.

Work described in this paper is to be submitted by A L G P for the MChir degree of the University of Cambridge

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